



# Interim Results

**24 November 2008**

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## Agenda



Introduction

Financial Update

Key Value Drivers

Summary

- ✔ Introduction & six month highlights
- ✔ Financial update
- ✔ Key value drivers
- ✔ Summary



A sustainably cash-generative specialty pharmaceutical business, investing for future revenue streams

- ❖ Product development, targeting lung pathologies
  - Develop/co-develop and out-license products that address larger markets
  - Develop/co-develop specialty products to regulatory approval and market
- ❖ Technology collaborations
- ❖ Building franchise through
  - Internal innovation
  - Acquisition of products, technologies or businesses

## Realising the vision



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- ✓ No requirement for further financing
- ✓ Careful cash management
  - Use revenues to offset costs
  - Build revenues
    - Short-medium term, with substantial milestones/royalties from current deals
    - Short-medium term, from future product/technology deals
    - Medium-long term from own-product sales
- ✓ Flexible development model
- ✓ Focused new product selection

# Vectura's future focus



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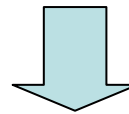
Key Value Drivers

Summary

Proven mechanisms/  
active drugs

Out-licensing or  
Specialty pharmaceutical  
potential

Vectura  
development or  
Co-development



Disease Areas  
of Interest

Lung pathologies

Neurological diseases

Respiratory  
e.g. Asthma, COPD

Other lung pathologies  
e.g. CF, IPF, HE, PAH

# The “universe” of lung pathologies



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Fibrotic disease	
Interstitial lung diseases	Idiopathic pulmonary fibrosis (IPF)
	Pulmonary fibrotic disease/ Pulmonary fibrosis (non-IPF only) <i>Secondary target: Asbestosis, Acute/Chronic berylliosis</i>
	Bronchiolitis obliterans organizing pneumonia (BOOP)
	Sarcoidosis
Cystic fibrosis	
Obstructive airway disease	
Alpha-1-Antitrypsin deficiency	
COPD	Chronic bronchitis
	Emphysema
Bronchiectasis	
Asthma	

Allergy	
Allergic bronchopulmonary aspergillosis	
Hypersensitivity pneumonitis	
Pulmonary eosinophilia	
Infectious lung disease	
Lower respiratory tract infections	Aspergillosis
	Bronchiectasis - infected
	Influenza
	Pneumonia
	Tuberculosis
	Whooping cough
	Legionnaires disease
Abscess of lung	

Lung cancer	
Malignant neoplasms of the respiratory system	Non-small cell lung cancer (NSCLC)
	Small cell lung cancer (SCLC)
Transplant rejection	
Lung acute rejection following lung transplantation	
Lung chronic rejection following lung transplantation	
Pulmonary arterial hypertension	
Sleep apnea	
Cough	

## Six month highlights



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### Financial results

- Revenues up 9%
- Net cash utilisation £5m
- Cash ~£74m



### Product highlights

- BI milestone - €7.5m
- Sandoz confirmed as partner on VR315 and VR632
- European Respiratory Society
  - Positive NVA237 Phase II data
  - Positive LAMA safety data from UPLIFT
  - Disappointing acridinium bromide Phase III data
- Start of VR496 Phase II trial in cystic fibrosis





## Financial update

**Anne Hyland**  
**Chief Financial Officer**

## Financial summary H1 2008/09



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**Revenues**

✔ **Up 9% to £13.3m**

**Gross Profit**

✔ **Up 17% to £11.4m**

**R&D Investment**

✔ **Up 10% to £16.1m**

**Cash**

✔ **£73.8m**

## Income statement H1 2008/09



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£m	2008/09 H1	2007/08 H1	2007/08 FY	Comments
<b>Revenue</b>	<b>13.3</b>	<b>12.3</b>	<b>25.2</b>	
Cost of sales	(1.9)	(2.5)	(4.4)	
<b>Gross profit</b>	<b>11.4</b>	<b>9.8</b>	<b>20.8</b>	
R&D costs	(15.4)	(13.8)	(28.0)	
Administrative costs	(1.3)	(1.7)	(3.1)	
<b>EBITDA</b>	<b>(5.3)</b>	<b>(5.7)</b>	<b>(10.3)</b>	
Amortisation/depreciation	(5.8)	(5.5)	(11.8)	
Share based compensation	(1.2)	(1.5)	(2.7)	
Share of loss of associate	(0.3)	(0.2)	(0.3)	
<b>Operating loss</b>	<b>(12.6)</b>	<b>(12.9)</b>	<b>(25.1)</b>	
Net financing income	2.0	1.7	3.7	Interest rate reduction will reduce H2 income
Exchange loss	(1.1)	-	-	\$19m financial liability offset by \$ royalty stream
<b>Pre-tax loss</b>	<b>(11.7)</b>	<b>(11.2)</b>	<b>(21.4)</b>	
Taxation	1.7	1.1	2.2	
<b>Loss after tax</b>	<b>(10.0)</b>	<b>(10.1)</b>	<b>(19.2)</b>	
<b>Loss per share</b>	<b>3.1p</b>	<b>3.2p</b>	<b>6.1p</b>	

## Revenues H1 2008/09



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£m	2008/09 H1	2007/08 H1	2007/08 FY	Comments
Royalties	5.9	4.5	9.1	Advate £3.9m, Extraneal £1.5m
Product licensing	0.5	1.7	2.3	
Technology licensing	2.8	1.4	3.4	£1.9m BI milestones
Pharmaceutical development services	3.1	4.1	8.9	
Device sales	1.0	0.6	1.5	
<b>Total revenues</b>	<b>13.3</b>	<b>12.3</b>	<b>25.2</b>	

## Cash flow highlights H1 2008/09



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£m	2008/09 H1	2007/08 H1	2007/08 FY	Comments
<b>EBITDA</b>	<b>(5.3)</b>	<b>(5.7)</b>	<b>(10.3)</b>	
Deferred income	(2.4)	(2.1)	2.4	
Working capital, etc.	1.0	1.8	4.2	
Net taxes received	0.4	0.2	2.2	
<b>Operating cash outflow</b>	<b>(6.3)</b>	<b>(5.8)</b>	<b>(1.5)</b>	-
Investing activities				
- Capital expenditure	(1.1)	(0.4)	(0.7)	
- Interest received	2.2	2.1	4.4	
- Receipts from sale of fixed assets			1.4	
<b>Cash outflow before financing</b>	<b>(5.2)</b>	<b>(4.1)</b>	<b>3.6</b>	
Financing activities				
- Financial liability/leases	-	(2.4)	(6.4)	
- Issue of shares	0.2	0.4	4.1	
<b>(Decrease)/increase in cash</b>	<b>(5.0)</b>	<b>(6.1)</b>	<b>1.3</b>	

## Balance sheet at 30 September 2008



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£m	As at 30 Sep 08	As at 31 Mar 08	Comments
<b>Non-current assets</b>	112.0	117.0	Amortisation of intangible assets reducing balance
<b>Current assets</b>			
- Inventory	0.1	0.2	
- Debtors, etc.	7.8	6.0	
- Cash, cash equivalents, short-term investments	73.8	78.8	
<b>Current liabilities</b>			
- Financial liabilities	(4.9)	(0.9)	
- Trade and other payables	(11.3)	(10.0)	
- Deferred income	(5.5)	(5.5)	
<b>Non-current liabilities</b>	(11.0)	(16.1)	£5.1m financial liability; £5.9m deferred income
<b>Shareholders' funds</b>	<b>161.0</b>	<b>169.5</b>	

## Financial guidance FY 2008/09



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### Revenue

- ✓ H208/09 in line with H1 at £13.3m
- ✓ Includes Boehringer Ingelheim £6m milestone received Nov 08 and recognised over 24 months - excludes any new milestones

### R&D

- ✓ Guidance H2 in line with H1 - FY circa £32m

### Administration

- ✓ FY circa £3m excluding amortisation and share based compensation

### Cash

- ✓ FY08/09 net cash burn £5m - £8m
- ✓ At lower end of previous guidance after receipt of £6m Boehringer Ingelheim milestone
- ✓ Net cash burn may increase if new in-licensing or co-development opportunities arise
- ✓ Net cash burn may decrease due to additional milestone or licensing receipts

## Major milestones after 30 September 2008



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- ✔ **NVA237/QVA149** - Circa \$85m prior to product launches in US & EU
- ✔ **VR315 EU** - €10m prior to product launch in major EU territories
- ✔ **VR315 US** - Up to \$30m prior to product launch in US
- ✔ **VR632 EU** - Up to €9m prior to product launches in main EU territories
- ✔ **BI** - In excess of €20m milestones per product approved for use in the inhaler
- ✔ **Duohaler<sup>®</sup>** - Up to £5m milestones per product prior to approval. 50% repayable in certain circumstances
- ✔ **Clickhaler<sup>®</sup>** - No further cash milestones due on current licensing deals





## Key value drivers

**Chris Blackwell**  
**Chief Executive**

# Targeting key value segments in the respiratory market



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# NVA237 & QVA149 - COPD

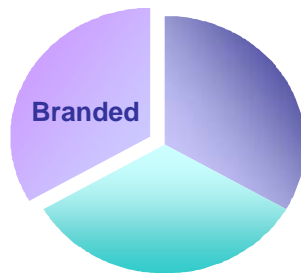


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- ✓ Collaboration signed in April 2005
- ✓ Upfront of \$15m received
- ✓ Milestones up to \$172.5m
- ✓ Royalties on product sales of NVA237 & QVA149
- ✓ Rights for additional third combination

## Monotherapy - NVA237

- ✓ Once-daily, long-acting, rapid onset muscarinic antagonist (LAMA)
- ✓ Phase II data presented at ERS demonstrating faster onset than Spiriva®

## Combination - QVA149

- ✓ Combination of NVA237 with indacaterol (QAB149), Novartis' long-acting, once-daily beta-agonist (LABA)
- ✓ Targeting neural modulators of bronchial tone, giving optimal effect



- ✓ NDA submissions scheduled from 2011

## Update from European Respiratory Society Meeting (ERS)



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- ✔ NVA237 Phase II dose-ranging and safety/tolerability
- ✔ Spiriva<sup>®</sup> safety data from UPLIFT
- ✔ Acclidinium bromide Phase III data

## NVA237 dose-ranging study in COPD - A2205, ERS 2008



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- ✔ Randomised, double-blind, placebo-controlled, x-over
- ✔ 83 patients >40yrs
  - (mean 64.4yrs)
- ✔ Smoking history >10 pack-years
- ✔ FEV<sub>1</sub> <80%, >30% predicted
  - (mean 1.3L)
- ✔ FEV<sub>1</sub>/FVC ratio <0.7
- ✔ NVA237 12.5, 25, 50, 100µg
- ✔ Tiotropium 18µg & placebo
- ✔ Once-daily treatment for 7 days

## NVA237 dose-ranging study in COPD - A2205, ERS 2008



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### Trough FEV<sub>1</sub> data – difference vs. placebo (95% CI)

NVA237 12.5µg	25µg	50µg	100µg	tiotropium 18µg
75ml (23,127)	90ml (37,143)	131ml (78,185)	142ml (89,195)	127ml (85,169)

$p \leq 0.002$  for all groups

Mean of data collected at 23.25 and 23.75 hrs post dose on Day 7



- ✔ Randomised, double-blind, placebo-controlled, parallel group
- ✔ 281 patients >40 years
  - Mean 63.4 years
- ✔ Smoking history  $10 \geq$  pack-years
- ✔ FEV<sub>1</sub>/FVC ratio <0.7
- ✔ FEV<sub>1</sub> <80%, >30%
  - (mean 1.3L)
- ✔ NVA237, 100µg and 200µg
- ✔ Once-daily treatment for 28 days

## NVA237 safety and tolerability in COPD - A2206, ERS 2008



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- ✓ NVA237 100µg & 200µg doses both well tolerated
- ✓ Low occurrence of dry mouth (3.3%, 7.1%, 0%)  
(100µg, 200µg, placebo)
- ✓ No clinically significant changes in QTc intervals
- ✓ No clinically significant changes in vital signs





## Trough FEV<sub>1</sub> difference vs. placebo at Day 28

NVA237 100µg	NVA237 200µg
161mL	151mL

$p < 0.05$

## NVA237 reports encouraging Phase II data



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- ✔ 24hr duration of effect on FEV<sub>1</sub>
- ✔ Evidence of more rapid onset of effect compared to tiotropium
- ✔ No safety concerns



- ❌ Singh *et al* (JAMA) claims elevated cardiovascular (CV) risk for inhaled anti-cholinergics
  - Retrospectively designed meta-analysis
  - Mixed analysis of muscarinic drugs
  - None of the trials included had CV risks as primary endpoint
  - Analysis did not have access to study source data
  - CV events were few raising doubts on clinical relevance (1.8% incidence vs. 1.2% in placebo)
  - Smaller patient numbers than Spiriva<sup>®</sup> meta-analysis (14,783 vs. 19,545) on 30 randomised controlled trials (RCTs)

Singh et al. JAMA 2008; 300 (12): 1439-1450

## Strong support for Spiriva<sup>®</sup> safety

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- ✔ Spiriva<sup>®</sup> meta-analysis of 30 RCT reverses concern over risk for stroke, MI and cardiac death
  - No increase in risk of all cause mortality, cardiac mortality, MI or stroke
- ✔ UPLIFT study reports out:
  - 5993 patients treated for 4 years
  - Failure to slow FEV<sub>1</sub> decline (primary EP)
  - Increase in mean FEV<sub>1</sub> in Spiriva<sup>®</sup> group on top of background COPD therapy (including Seretide<sup>®</sup> /Advair<sup>®</sup>)
  - Improved QOL for Spiriva<sup>®</sup> group
  - Reduction of all cause mortality in Spiriva<sup>®</sup> group

## Disappointing Phase III results for acclidinium bromide



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- ✔ ACCLAIM I & II total 1647 patients
- ✔ Patients had moderate to severe COPD
  - > 40 years old
  - >10 pack-years smoking history
  - Mean FEV<sub>1</sub> 1.4L and 1.2L
- ✔ Once daily dosing with acclidinium 200µg vs. placebo via Genuair® inhaler for 1 year
- ✔ Trough FEV<sub>1</sub> increase vs. placebo was 60 - 70 mL at weeks 12 & 28 (p<0.001)
  - Maintained over 52 weeks (p<0.001)
- ✔ Peak FEV<sub>1</sub> increase vs placebo was 154 -177mL at weeks 12 & 28 (p<0.0001)
- ✔ Median time to peak FEV<sub>1</sub> = 2 hours
- ✔ QOL and time to first exacerbation end points each missed significance in one trial
- ✔ Safety and tolerability comparable for both treatment arms

## VR496 – Cystic fibrosis/COPD

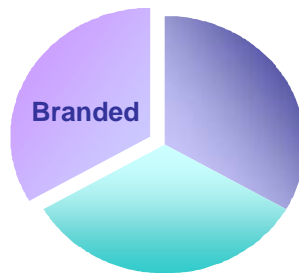


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- ✓ Phase II CF study initiated October 2008
  - ✓ Speciality product that Vectura can take through to market
  - ✓ Global CF market predicted to increase from \$680m in 2008 to \$1.93b in 2015
  - ✓ Potential utility in COPD – opportunity to partner for this indication
- ✓ Double-blind, placebo controlled randomised trial with 4-week at-home treatment period
  - ✓ 64 patient study
  - ✓ Three study doses plus placebo
  - ✓ Study end points
    - Safety
    - Lung function (FEV<sub>1</sub> and FVC)
    - Anti-inflammatory activity
      - Neutrophil elastase and IL-8 in induced sputum
    - Mucolytic activity
      - Mucociliary clearance (PRO via diary card)
      - Sputum viscosity
    - Microbiological bacteria count and density (expectorated sputum)
    - Cystic Fibrosis Questionnaire (CFQ-R)

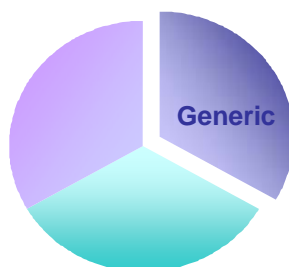
## VR315 – Asthma/COPD

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**Key Value Drivers**

Summary



- ✓ An inhaled combination asthma/COPD therapy
- ✓ In development as a generic product delivered with Vectura's GyroHaler®
- ✓ Registration trials scheduled for 2008

### Europe

- ✓ Licensed to Sandoz (March 2006)
- ✓ €22.5m in milestones and development funding
- ✓ Royalties on all VR315 sales and a margin on the commercial manufacture and supply of GyroHaler®

### US

- ✓ Cost share/profit share agreement with Sandoz (December 2006)
- ✓ Up to \$63m upon achievement of pre-determined milestones

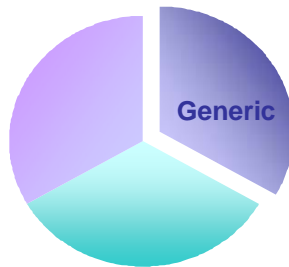
## VR632 – Asthma/COPD

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- ✓ An inhaled combination asthma/COPD therapy
- ✓ In development as a generic product delivered with Vectura's GyroHaler®
- ✓ Licensed to Sandoz for Europe only
- ✓ Vectura retains US rights; non-generic product opportunity

- ✓ €15.5m in milestones and development funding
- ✓ Royalties on all VR632 sales and a margin on the commercial manufacture and supply of GyroHaler®



## Top 5 respiratory products 2007



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Advair®/Seretide®	\$6.9B	Diskus® / Accuhaler®
Singulair®	\$4.3B	Oral
Spiriva®	\$2.9B	Handihaler® / Respimat®
Symbicort®	\$1.6B	Turbohaler®
Pulmicort®	\$1.5B	pMDI / DPI (Turbohaler®) / nebulised

## Boehringer Ingelheim collaboration

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- Development of a dry powder inhaler to deliver BI proprietary respiratory products
- Building on Vectura's GyroHaler® technology
- Creating value from Third Party respiratory products



- Worldwide collaboration, development and licence agreement (May 2006)
- €5 million in cash & €10m in equity at a premium on signing
- Milestone of €10m in cash & €5m in equity at a premium (Nov 2007)
- Milestone of €7.5m in cash (Oct 2008)
- Further milestones on every product developed in the device
- Royalties on product sales

## BI's marketed products & respiratory pipeline

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### ✔ Marketed products

- Spiriva<sup>®</sup> (tiotropium)
- Atrovent<sup>®</sup> (ipratropium bromide)
- Combivent<sup>®</sup> (ipratropium bromide/salbutamol)
- Berodual<sup>®</sup> Duovent<sup>®</sup> (fenoterol/ipratropium bromide)

### ✔ Limited public information on respiratory pipeline

- Number of ipratropium and tiotropium clinical trials
  - Tiotropium/salmeterol
  - Tiotropium/formoterol
- Two other molecules in clinical trials but limited information
  - BI 1744 CL  $\beta_2$ -agonist (Phase II)
  - BEA 2180 BR anti-inflammatory (Phase II)



## Summary

**Chris Blackwell**  
**Chief Executive**

## Near-term newsflow

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✓ VR040 Parkinson's disease

✓ VR315 Asthma/COPD

✓ NVA237 COPD

✓ QVA149 COPD

✓ Duohaler<sup>®</sup>

✓ VR496 CF

“At home” study start

Registration studies

Registration studies

Registration studies

Registration studies

Phase II (p-o-c) data

## Summary

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- ✔ One of the broadest pipelines in the sector
  - 8 marketed products
  - 1 Phase III product
  - 8 Phase II products
- ✔ Out-licensing opportunities
  - Technologies and products
- ✔ Strong financial position
  - Targeting sustainable cash generation
  - Growing revenue streams
  - ~ £74 million cash at 30 September 2008
- ✔ High value respiratory pipeline
  - 4 products in preparation for registration studies



A leader in inhaled pharmaceuticals



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